CHAPTER 33B

EXTRACORPOREAL SHOCK WAVE LITHOTRIPSEY

Authority

N.J.S.A. 26:2H–1 et seq.

Source and Effective Date

R.1990 d.418, effective July 27, 1990.
See: 22 N.J.R. 1495(a), 22 N.J.R. 2506(b).

Executive Order 66(1978) Expiration Date

Chapter 33B, Extracorporeal Shock Wave Lithotripsey, expires on July 27, 1995.

Chapter Historical Note

Chapter 33B, Extracorporeal Shock Wave Lithotripsey, became effective October 7, 1985 as R.1985 d.497. Pursuant to Executive Order No. 66(1978), Chapter 33B was readopted as R.1990 d.418. See: Source and Effective Date.

See section annotations for specific rulemaking activity.

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SUBCHAPTER 1. LITHOTRIPTER SERVICES

8:33B–1.1 Introduction

(a) Extracorporeal shock wave lithotripsey (ESWL) is a newly developed, Medicare approved therapeutic modality designed to treat upper ureter and kidney stones non-invasively. Shock waves are externally introduced into the body thereby creating sufficient pressure on a stone so that the stone disintegrates eventually crumbling into granular sized particles. The particulate residue of the stone is then eliminated with the urine.

(b) Extracorporeal shock wave lithotripsey treatment offers both promising benefits to patients and to the health system. Because it can destroy stones without surgery, it eliminates risk associated with surgery, reduces the length of time a patient must be hospitalized, and reduces the costs associated with kidney stone removal. The average length of stay associated with conventional surgical removal of kidney stones is between seven and 14 days. The recuperative period following discharge is usually three to four weeks. The average length of stay associated with ESWL is four days. Most patients are then able to fully resume their lifestyle within a week of discharge.

(c) The Department of Health recognizes that the introduction of the lithotripter will have profound implications for kidney stone patients. However it also raises a number of planning issues which must be given serious consideration. Namely, the lithotripter device is costly in itself and additional renovation and/or construction costs to house the unit can bring the total cost to over $2 million. In addition to cost, another issue which needs to be addressed is the lithotripter's application for a very limited and specific population. ESWL can potentially replace surgical intervention in 80–90 percent of those patients for whom surgical removal of kidney stones would have been the only treatment of choice. The device however is limited in application solely to this population. The Department is also concerned about the impact of the growing acceptance of other new stone treatment modalities such as percutaneous lithotripsey and newly developed drugs that selectively inhibit stone formation.

(d) The demonstration period will provide the Department with the opportunity to evaluate and analyze findings as they relate to planning concerns.

8:33B–1.2 Definitions

The following words and terms, when used in the subchapter, shall have the following meanings:

"Department" means the New Jersey Department of Health.

"Extracorporeal shock wave lithotripsey (ESWL)" means the technique by which kidney stones are disintegrated through the use of shock waves sent through water.

"Lithotripter" means a medical device which removes kidney stones without surgical intervention.

8:33B–1.3 Demonstrations

(a) The Commissioner of Health will establish a lithotripter demonstration period during which three applications will be approved Statewide.

(b) The Statewide demonstration period will begin with the date of initial operation of the first approved unit and will continue for a period of two years and six months. However the demonstration period can be shortened by the Commissioner of Health upon the recommendation of the Statewide Health Coordinating Council. The applicant will be required to identify in its application the anticipated date of initial operation.

(c) Once the demonstration approvals, three units Statewide, are issued, the Department of Health shall not process any other applications for lithotripters until the conclusion of the demonstration period, not to exceed two years and six months, beginning with the date of operation of the first lithotripter demonstration.

(d) The Commissioner of Health in issuing approvals for lithotripter demonstrations shall solicit the recommendations of the Statewide Health Coordinating Council (SHCC) and each of the State's five Health Systems Agencies (HSAs).

(e) During the demonstration the Department will limit applications for lithotripters to hospitals filing separately or consortia which include either hospital members exclusively or hospital members filing jointly with other interested parties.

(f) Preference in the placement of the lithotripter demonstration units shall be given to teaching hospitals filing Certificate of Need applications either separately or jointly with other interested parties.

Public Notice: There will be a third site proposed for the demonstration of ESWL services.
See: 18 N.J.R. 1314(a).
Amended by R.1986 d.259, effective July 7, 1986.
See: 18 N.J.R. 798(a), 18 N.J.R. 1379(b).
A third site was adopted for the demonstration of ESWL services.
Public Notice: The Health Care Administration Board is proposing to extend the demonstration period for Extracorporeal Shock Wave Lithotripsey Services.
See: 20 N.J.R. 816(a).
Amended by R.1988 d.322, effective July 18, 1988.
See: 20 N.J.R. 869(b), 20 N.J.R. 1690(a).
Added six months.

8:33B–1.4 Utilization

(a) Utilization standards are based on the number of patients who may receive ESWL treatment.

(b) Volume of patients diagnosed with and hospitalized for urinary calculi located in either the kidney or upper ureter is an indicator of potential ESWL candidates. Applicants must therefore document sizable volumes of patients diagnosed and surgically treated by the applicant for removal of calculi located in the upper ureter or the kidney during the past three years.

(c) In order to maintain quality and deliver this service in a cost-effective manner, the applicant must document the availability of a minimum volume of ESWL patients. The minimum acceptable number of ESWL patients per device per year is 500. For purposes of reviewing applications in the demonstration batch, priority shall be given to applicants who can demonstrate volumes above the minimum acceptable number.

8:33B–1.5 Personnel requirements

(a) Each applicant for a certificate of need for a lithotripter must provide the Department with written documentation that the following minimal staff complement will be available on a full time basis to the ESWL unit.

1. 1.0 urologist/surgeon;
2. 1.0 registered nurse;
3. 1.0 anesthesiologist;
4. 1.0 technician.

(b) In addition, sufficient supportive personnel consistent with the efficient delivery of quality ESWL services should be assigned to the ESWL unit (for example, aides, secretaries, clerk).

8:33B–1.6 Program considerations

(a) Applicants must have the following available at a minimum, either on site or through formal, written agreements:

1. Active radiology and urology programs;
2. Teaching and research backup;
3. An established referral urological practice; and
4. An appropriate specialty backup.

8:33B–1.7 Data requirements

(a) The following information shall be reported by the applicant on a bi-annual basis to the Department of Health's Health Planning Services Program:

1. Characteristics of patients: age, sex, residence, insurance coverage, specific diagnosis, source of referral;
2. Treatment protocols and selection criteria;
3. Type of anesthesia used, for example, general, epidural or spinal; length of treatment (including preparation time), length of hospitalization, length of recuperative period;
4. Staff requirement (by type of personnel) for the ESWL treatment;
5. Expenses and revenues relating to lithotripsey treatments will be separately identified on cost reporting forms which must be submitted to the Department on an annual basis;
6. Adverse patient reactions and contra-indicators.

8:33B–1.8 Accessibility

(a) Applicants must document that ESWL services shall be made available to all patients regardless of the patients' race, religion, sex, age or ability to pay.

8:33B–1.9 Regional distribution—cooperative multi-institution applications

(a) Recognizing that the lithotripter will have application for a limited and select population, the device lends itself to regional distribution with the following requirements:

1. Applicants must develop cooperative agreements with other institutions;

2. Shared or multi-institution applicants must provide formal written agreements providing for inter-hospital referral and transfer agreements. The purpose for these arrangements is to insure adequate followup after the lithotripsey treatment.

8:33B–1.10 Financial criteria

The applicant must provide full written documentation of the purchase and operational costs of the unit. This analysis must include direct as well as indirect costs, construction/renovation costs, and cost impact analysis upon radiology and urology departments. In addition, the application must include a projection of costs and revenues to at least two years beyond the breakeven point.

8:33B–1.11 Physical requirements

The applicant must provide physical plans showing adequate space to house the unit, accommodate patient needs (pre- and post-treatment), and support staff needs. The plans must be reviewed and approved by the New Jersey Department.

8:33B–1.12 Reimbursement

(a) In establishing reimbursement to applicants who have been approved as demonstration sites for ESWL services, the Department shall develop a Statewide technical fee for ESWL treatment based on reasonable costs for the provision of ESWL treatment services.

New Rule R.1986 d.259, effective July 7, 1986.
See: 18 N.J.R. 798(a), 18 N.J.R. 1379(b).